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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,405	08/11/2006	John W. Babich	346715-0626 NATL	8331
48329	7590	09/07/2010		
FOLEY & LARDNER LLP 111 HUNTINGTON AVENUE 26TH FLOOR BOSTON, MA 02199-7610			EXAMINER JONES, DAMERON LEVEST	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 09/07/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/589,405

**Applicant(s)**

BABICH ET AL.

**Examiner**

D L. Jones

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 8/11/06 & 6/30/10.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28-30 and 54-136 is/are pending in the application.  
4a) Of the above claim(s) 28-30, 54-73, 77-132 and 134-136 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 74-76 and 133 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 11 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Prioritization's Patent Drawing Review (PTO-544)  
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/7/07; 3/26/09; 9/4/09; 11/25/09; 4/20/10;& 5/26/10.

## ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 8/11/06 wherein the specification was amended; claims 1-27, and 31-53 were canceled; and claims 133, 134, and 136 were amended.

**Note:** Claims 28-30 and 54-136 were pending.

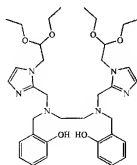
## APPLICANT'S INVENTION

2. The instant invention is directed to various heteroaryl compounds and uses thereof.

## RESPONSE TO APPLICANT'S ELECTION

3. Applicant's election of Group III (claims 58-95 and 133) in the reply filed on 6/30/10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Hence, the restriction requirement is still deemed proper and is therefore made FINAL.

4. Applicant elected Formula H and the species of Example 4, as set forth below:



. Initially, Applicant's elected species was searched.

However, since there was no prior art tot reject the elected species, the search was

expanded to that disclosed in Gregory (US Patent No. 2,863,874) disclosed below. The search was not further expanded because prior art was found to reject the claims.

#### **WITHDRAWN CLAIMS**

5. Claims 28-30, 54-73, 77-132, and 134-136 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

#### **112 FIRST PARAGRAPH REJECTION (Written Description)**

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 74-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant

application does not sufficiently describe the invention as it relates to the ligands for a G-protein coupled receptor, the lipophilic groups, the neutral or anionic Lewis bases, and the amino acid radicals that are encompassed by the instant invention. Applicant is reminded that while a generic claim may define the boundaries of a vast genus of chemical compounds (i.e., ligands for a G-protein coupled receptor, the lipophilic groups, the neutral or anionic Lewis bases, and the amino acid radicals), the question may still remain whether the specification demonstrates that Applicant invention species sufficient to support a claim to a genus. In this particular instance, the issue is especially acute with genus claims that use functional language to define the boundaries of a claimed genus. Thus, the functional claims are directed to a desired result (i.e., a lipophilic moiety to a compound that will increase the compound's affinity for octanol in the standard octanol/water partition coefficient determination protocol; see how Applicant defined 'lipophilic moiety' on page 9, paragraph [0054] of US 2008/0025915) wherein specific species that achieve that result are not disclosed. However, one is reminded that the specification must demonstrate the Applicant has made a generic invention that achieves the claimed result and do so by showing that the Applicant has invented species sufficient to support a claim to the functionally defined genus. As a result, what the Reader gathers from the instant application is a desire/plan/first step for obtaining a desired result. While the Reader can certainly appreciate the desire for achieving a certain end result, establishing goals does not necessarily mean that an invention has been adequately described.

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description is necessary to practice an invention described only in terms of its function and/or based on a disclosure wherein a description of the components necessary in order for the invention to function are lacking. In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed. Thus, the written description requirement is lacking in the instant invention since the various terms as set forth above are not described in a manner to clearly allow persons of ordinary skill in the art to recognize that Applicant invented what is being claimed.

## **112 SECOND PARAGRAPH REJECTION**

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 74-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 74-76: The claims as written are ambiguous because it is unclear what ligands for a G-protein coupled receptor, lipophilic group, neutral or anionic Lewis base, and amino acid radical (see claim 74, lines 17, 18, 19, and 23) Applicant is claiming

that is compatible with the instant invention. For example, a radical, according to any standard chemical dictionary (i.e., Lewis, Hawley's Condensed Chemical Dictionary, 1993, page 990) is defined as an ionic group having one or more charges either positive or negative. Thus, depending upon which portion of the structure is removed from the amino acid, one cannot ascertain which portion of the amino acid remains.

## 102 REJECTION

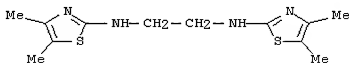
10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 74-76 and 133 are rejected under 35 U.S.C. 102(b) as being anticipated by Gregory (US Patent No. 2,863,874).

**Gregory** discloses a methods of preparing 2-aminothiazoles (see entire document, especially, abstract). In particular, Gregory disclose the compound, N,N'-[(2,4,5-dimethylthiazyl)ethylene diamine (column 6, lines 55-58; column 14, lines 52-57),



having the structure: . Thus, Gregory discloses a species that meets the requirements of the instant invention when Applicant's variables have the following values:  $m = 0$ ;  $n = 0$ ;  $R_3 = H$ ;  $X = \text{sulfur}$ ; and  $R = \text{alkyl}$  (e.g., methyl). Hence, both Applicant and Gregory disclose overlapping subject matter.



**PRIORITY DOCUMENT**

12. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

**SPECIFICATION**

13. The disclosure is objected to because of the following informalities: the information on the bibliography data sheet and application data sheet filed 8/11/06 and 6/5/07 is not consistent with that of the first paragraph in the specification. Specifically, the specification references 10/386,403 and 60/363,142. In addition to 60/543,986 and 60/566,635 (both listed on the bibliographic sheet). Thus, it is unclear which set of data is correct. Applicant is respectfully requested to clarify the record.

Appropriate correction is required.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/  
Primary Examiner  
Art Unit 1618

September 1, 2010